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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,824	01/06/2006	Katsuaki Kurihashi	TAN-C533	1622

7590 12/03/2009

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EXAMINER	
WIEST, PHILIP R	
ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
12/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,824	KURIHASHI, KATSUAKI	
	Examiner	Art Unit	
	Philip R. Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/09 has been entered.

Response to Amendment

In the reply filed 10/22/09, applicant amended claim 19 and added new claims 27-32. Claims 19-32 are currently pending.

Response to Arguments

Applicant's arguments with respect to claims 19-26 have been considered but are moot in view of the new ground(s) of rejection.

It is important to note that the amendments to claim 19 (and corresponding language in Claim 27) with respect to the method of using the thread are functional language. Because Claims 19 and 27 are device claims, a device must only be *capable* of performing in this manner in order to meet the limitations of the claims. The newly-discovered Li reference reasonably suggests an alternate means for attaching a thread (or suture) to a medical implant, such that the implant is capable of being retracted

toward the applicator. Further, the suture is capable of being removed from the implant by cutting one side of the suture loop and threading the severed end of the suture through the aperture of the implant (see rejection below).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 19-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herrick '684 (US 6,290,684) in view of Herrick '270 (US 5,171,270), and further in view of Li et al. (US 2003/0125748). Herrick '684 teaches a punctal plug comprising a shaft, a tip portion (190, 212; see Figure 9), a disc-shaped brim 244 attached to the shaft opposite the tip. A protuberance 208 is attached to the tip portion such that the plug is capable of sealing the punctum opening of the eye. Herrick '684 teaches the device substantially as claimed, but does not specifically teach that the punctum plug comprises a loop of thread attached to the plug for pulling out the plug from the punctum opening.

Herrick '270 teaches a canalicular implant for insertion into the punctum of an eye, said implant comprising a pointed tip and a flared, flexible brim. The implant comprises a thread-like member 44 for removing the implant from the eye. Herrick '270 teaches that the application of a pulling force to the implant by means of a thread allows

an implant to be easily removed through the punctum of the eye, thereby preventing the need for more invasive means for removing a punctum-canaliculus plug. The use of thread-like members to remove an implanted plug from a patient's punctum is thereby established in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the punctum plug of Herrick '684 with a thread attached to the brim of the implant, as taught by Herrick '270, in order to provide a well known means for removing the implant from the body. Regarding the specific diameter of the thread, it has been held that mere changes in size or proportion do not constitute patentable improvements in the art when new and unexpected results are not realized (see MPEP § 2144.04. IV. A.). In this case, it is obvious that small threads should be used in order to reduce the volume of material that must be inserted into the patient's body. One of ordinary skill in the art at the time of invention would have recognized that reducing the diameter of the thread would reduce the overall volume and bulk of the implant being inserted into the patient's punctum. Reducing the diameter of the thread does not provide a new and unexpected result.

Herrick '270, however, does not teach that the thread-like member comprises a *loop* of thread that passes through the implant in a manner such that the thread terminates at two free ends extending from the plug.

Li et al. (hereafter Li) teaches an implant delivery device wherein the implant is attached to the device by a suture loop. The suture loop 160 having two opposing ends passes through an aperture 162 extending through the implant 102 so as to allow it to be retracted toward the delivery device upon activation of an actuator 170 (by means of

pulling on the opposing ends of the suture loop). The suture loop is fully capable of being removed from the implant at any time. Specifically, to remove the suture loop, one end of the loop is cut, such that the severed portion of the suture may be pulled through the aperture of the implant (see [0067]). When compared to Herrick's thread-like member, Li's use of a loop-type string provides similar functionality of providing an alternate means for pulling an implant rearward, toward the applicator. Li's suture loop configuration, however, provides the additional functionality of allowing the thread-like member to be removed from the implant once it is no longer needed. Therefore, it would have been obvious to one of ordinary skill in the art to modify the implant of Herrick '270 with Li's suture loop retraction means in order to provide a well-known, alternate means of retracting the implant toward the applicator. Doing so would provide the additional functionality of allowing the thread to be easily removed from the plug, thereby allowing the plug to be permanently implanted if so desired.

3. Regarding Claims 21-23 and 29, Herrick '684 teaches an implant that is configured to be inserted into the punctum of the eye to prevent fluid flow therethrough, but does not specifically teach the claimed dimensions of the brim. However, mere changes in size or proportion do not constitute patentable improvements in the art when new and unexpected results are not realized (see MPEP § 2144.04. IV. A.). In this case, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the size of the implant and brim in order to meet the needs of a specific patient or application.

4. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herrick '684 (US 6,290,684) in view of Herrick '270 (US 5,171,270) and Li et al. (US 2003/0125748), and further in view of Fogarty (US 6,168,623). Herrick '684, Herrick '270, and Li reasonably suggest the device substantially as claimed, but do not specifically teach that the plug comprises a reinforcing member. However, it is known that punctal plugs must be substantially soft, such that the outer surface is capable of deforming to match the shape of the patient's punctum. Fogarty teaches an implantable medical shunt comprising a metal coil that reinforces the shape of the shunt, thereby maintaining the intended shape of the shunt once it has been implanted (Column 11, Lines 3-21). The use of internal metal coils to reinforce medical implants is well known in the art because it substantially maintains the intended shape of a flexible implant once it is inserted into the body. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the punctum plug of Herrick with Fogarty's internal metal coil because doing so would substantially maintain the intended shape of the flexible plug once it is inserted into the punctum.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
1 December 2009